UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,106	12/21/2001	Jean-Christophe Renauld	LUD 5752 DIV JEL/NDH (101	7513

24972 7590 03/04/2004

FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,106	RENAULD ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,24,25 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,24,25 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 02 December 2003 has been entered in full. Claims 1 and 29 are amended. Claims 13-23, 26-28, and 30-37 are cancelled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

It is noted that Supervisory Primary Examiner, Gary Kunz, spoke with Mr. Norman Hanson on 02 March 2004 to discuss the relatedness of SEQ ID NOs: 7, 8, 9, and 10. Mr. Hanson indicated that SEQ ID NOs.: 8 and 10 are identical through amino acid 177, where 4 amino acids that are present in SEQ ID NO: 8 are missing in SEQ ID NO: 10. Mr. Norman, in the response of 02 December 2003, indicated that the sequences were related and performed the same function. These arguments are found to be persuasive. The amino acid sequence of SEQ ID NO: 10 has been rejoined to the group of amino acid sequence of SEQ ID NO: 8. The nucleotide sequence of SEQ ID NO: 9 has been rejoined to the group of nucleotide sequence SEQ ID NO: 7.

Claims 1-12, 24-25, and 29 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objection to claims 1-3 and 29 at pg 4 of the previous Office Action (29 September 2003) is *withdrawn* in view of Applicant's persuasive arguments (02 December 2003).

2. The objections to the specification at pg 4-5 of the previous Office Action (29 September 2003) are withdrawn in view of the amended specification and cancellation of the Figures (02 December 2003).

3. The rejections of claims 1-12, 24-25, and 29 under 35 U.S.C. § 112, second paragraph, at pg 8-9 of the previous Office Action (29 September 2003) are withdrawn in view of the amended claims (02 December 2003).

Claim Rejections - 35 USC § 101 and 35 USC 112, first paragraph

4. Claims 1-12, 24, 25 and 29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The basis for this rejection is set forth at pg 5-7 of the previous Office Action (29 September 2003).

Claims 1-12, 24, 25 and 29 of the instant invention are directed to an isolated nucleic acid molecule which encodes a cytokine receptor, wherein the complementary nucleotide sequence hybridizes under stringent conditions to SEQ ID NO: 7 or SEQ ID NO: 9. The claims also recite a nucleic acid molecule encoding a polypeptide that comprises the amino acid of SEQ ID NO:8 or SEQ ID NO: 10. The claims recite an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 7 or SEQ ID NO: 9. The claims recite a vector comprising said nucleic acid, a recombinant host cell comprising said vector and a method of producing the encoded protein. Additionally, the claims recite an isolated oligonucleotide consisting of anywhere from 17 up to 100 contiguous nucleotides of the nucleotide sequence of SEQ ID NO: 7 or SEQ ID NO: 9.

Applicant's arguments (02 December 2003), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Applicant asserts that in the specification of the instant application (pg 7-8, example 7), cells were transfected with a chimeric receptor (IL-10R/LICR-2). Applicant argues that this chimeric receptor includes the intracellular portion of LICR-2. Applicant indicates that the cells are exposed to IL-10, and in a control, to IL-22. Applicant states that a luciferase assay was carried out and cells contacted with IL-10 did cause activation of STAT factors. Applicant asserts that LICR-2 can and does activate STAT factors.

Applicant's arguments have been fully considered but are not found to be persuasive. Specifically, this asserted utility is not specific or substantial. Such assays can be performed with any polynucleotide/polypeptide. Relevant literature teaches that STAT proteins, a family of transcription factors in a cell's cytoplasm, become activated by a variety of soluble factors, such as cytokines, growth factors, and hormones that bind to specific cell surface receptors (Calo et al. J Cell Physiol 197: 157-168, 2003; pg 157, ¶ 2). Therefore, since many receptors can activate the same STAT substrate by phosphorylating the tyrosine residue, this asserted utility is not specific (pg 158, col 2, first full paragraph). Additionally, STAT proteins play different roles in normal physiological cell processes, such as proliferation, differentiation, angiogenesis, and apoptosis (pg 157, ¶ 2). Although LICR-2 may be involved in the activation of STAT factors in general, the specification of the instant application does not teach the biological activity or cell processes associated with LICR-2. Regarding example 7 (pg 7-8), it is also not clear to the Examiner why the entire structure of LICR-2 was not utilized in any assay. If AK155 is the ligand for LICR-2, why weren't cells transfected with LICR-2/reporter gene and then incubated

with AK155? Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

5. Claims 1-12, 24, 25 and 29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth at pg 5-8 of the previous Office Action (29 September 2003).

6. Furthermore, claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 29 recites an isolated oligonucleotide consisting of anywhere from 17 up to 100 contiguous nucleotides of the nucleotide sequence set forth in SEQ ID NO: 7 or SEQ ID NO: 9.

The specification teaches that "a 'fragment' of a polypeptide generally means a stretch of amino acid residues of at least about five contiguous amino acids, often at least about seven contiguous amino acids, typically at least about nine contiguous amino acids, more preferably at least about 13 contiguous amino acids, and, more preferably, at least about 20 to 30 or more contiguous amino acids. A peptide fragment may be 5, 6, 7, 8, 9 or 10, 5 to 10, 5 to 20, 10 to 20, 10-30, 20-30, 20-40, 30-40 or more than 40 amino acids in length" (pg 13, lines 27-31; pg14, line 1). However, the specification does not teach any polynucleotide fragments of SEQ ID NO:

7 or SEQ ID NO: 9 or any polypeptide fragments of SEQ ID NO: 8 or SEQ ID NO: 10. Additionally, the specification does not teach functional or structural characteristics of any polynucleotide fragments in the context of a cell or organism.

The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and DNA is extremely complex. For example, while it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein and DNA which are tolerant to change and the nature and extent of changes that can be made in these positions. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Conclusion

No claims are allowable

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Wednesday-Thursday 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
03 March 2004

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600